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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/518,190	03/02/2000	John Edward Hesketh	0623.0820001/REF	4790

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EXAMINER

LANDSMAN, ROBERT S

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 11/08/2002

98

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/518,190

Applicant(s)

HESKETH ET AL.

Examiner

Robert Landsman

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-16 and 21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-16 and 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the FINALITY of that action is withdrawn and prosecution on the merits continues.

1. Formal Matters

- A. Amendment D, filed 8/8/02, has been entered into the record.
- B. Claims 9-16 and 21 are pending in this application and are the subject of this Office Action.
- C. All Statutes under 35 USC not found in this Office Action can be found, cited in full, in a previous Office Action.

2. Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

- A. Claims 9-12, 14-16 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Scott et al. (JBC 271(3):1605-1612, 1996). The claims recite a nucleic acid molecule encoding a mammalian signal peptide from a protein normally secreted from a mammalian cell operatively linked to a nucleic acid encoding a protein that would not normally be secreted from a mammalian cell, wherein the nucleic acid is either DNA or RNA. The claims also recite vectors, cells and methods of obtaining the protein.

Scott et al teach a nucleic acid molecule (cDNA) encoding a mammalian signal peptide (HA) linked to the intracellular protease inhibitor, PI-6, a protein which is not normally secreted from the cell (Abstract), as well as vectors comprising this nucleic acid molecule (page 1606 under "Plasmids"). Scott et al. also teach mammalian cells comprising this nucleic acid (COS-7 cells on page 1605 under "Cell Culture") and a method of producing this protein (page 1606 under "Assay for secretion of PI-6 from Cultured Cells"). The reference does not teach the use of RNA. However, one of ordinary skill in the art would immediately envision the RNA sequence given the cDNA sequence of Scott et al. Scott et al. meet the limitation of chimeric protein since the PI-6 nucleic acid molecule of Scott et al. was linked to a signal sequence and this PI-6/signal sequence was translated, producing a chimera.

Art Unit: 1647

3. Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

A. The rejection of claims 9-16 under 35 USC 103 as being unpatentable over Kordula et al. in view of Lee et al. and further in view of Maeda et al. have been withdrawn in view of Applicants' arguments. However, the following rejection moots Applicants' arguments provided in amendment D, filed 8/8/02 since Scott et al. teach a nucleic acid with a disrupted 3'-UTR linked to a mammalian signal sequence as well as a mammalian host cell.

B. Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scott et al. in view of Sleep et al. (Biotechnology 8(1):42-46, 1990). The teachings of Scott et al. are recited in the above rejection under 35 USC 102. Scott et al. do not teach the use of an albumin protein signal sequence. However, Sleep et al. do teach the use of a human serum albumin signal sequence to secrete a protein. Therefore, it would have been obvious to one of ordinary skill in the art to have substituted numerous signal sequences, including the human serum albumin signal sequence of Sleep et al., for the HA signal sequence of Scott et al. in view of the suggestion by Sleep et al. that it would be desirable to do so. Sleep et al. teach that in designing secretion systems for heterologous proteins, one aims to maximize both the yield and fidelity of the product and that the choice of leader sequence and its relationship to the structural protein under study are crucial to the success of the protein. One of ordinary skill in the art would have had a reasonable expectation of success in substituting human serum albumin signal sequence of Sleep et al., for the HA signal sequence of Scott et al. since molecular cloning techniques were well-known and highly successful at the time of the present invention, as evidenced by their successful use by Scott et al. and Sleep et al. Though claim 12 was rejected in the above rejection under 35 USC 102, it is also being included in this rejection since Scott et al. is silent regarding the origin of the HA signal sequence. Therefore, in the situation where the HA signal sequence is not from a mammal, claim 12 would also be rendered obvious in view of the teachings of Sleep et al.

Art Unit: 1647

4. Conclusion

A. No claim is allowable.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.
Patent Examiner
Group 1600
November 06, 2002

Gary L. Kunz
GARY KUNZ
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